REMARKS

Claims 1-39 are pending and under examination in the above-identified application. Claims 14, 21, 23, 35, 36 and 37 have been amended above. Claims 19 and 20 have been cancelled. Support for the amendments can be found throughout the application and in cancelled claims 19 and 20. Accordingly, the amendments do not raise an issue of new matter and entry thereof is respectfully requested. Applicant has review the rejections set forth in the Office Action mailed May 26, 2005, and respectfully traverse all grounds for the reasons that follow.

Applicant would like to thank Examiner Forman for extending a personal interview with Applicant and Applicant's representatives on August 9, 2005. The amendments above and remarks below are believed by Applicant to substantially conform to the subject matter discussed in the interview. Reconsideration of the rejection is respectfully requested.

Applicants maintain that the Office Action mailed May 26, 2005, should be a non-final Action. As acknowledged at page 2 of the Office Action, Applicants submitted a Request for Continued Examination (RCE) together with a submission satisfying all requirements of 37 C.F.R. § 1.114. However, relying on M.P.E.P. § 706.07(b), the Office makes final the rejections in the pending Office Action (see page 9, second paragraph). M.P.E.P. § 706.07(b) states in pertinent part:

> [I]t would not be proper to make final a first Office action in a continuing or substitute application where that application contains material which was presented in the earlier application after final rejection or closing of prosecution but was denied entry because . . . new issues were raised that required further consideration and/or search.

Id.

Applicants amended claims 14, 21, 23, 35, 36 and 37 in the RCE filed on March 9, 2005, to recite that the plurality of different target analytes are attached to each of the microspheres. This amendment was presented to the Examiner during a personal interview on November 22, 2004, who indicated in the Summary record:

> [A]ny amendments would require further search and consideration and therefore would not be entered after final.

Interview Summary dated November 26, 2004, at page 4.

Based on this representation, Applicant filed a RCE in order to further prosecution and to ensure the non-finality of any first Office Action that would issue in the event the claims were not deemed allowable. Accordingly, the finality of the pending Office Action is unwarranted. Applicants have satisfied all requirements for furthering prosecution through an RCE and have satisfied the requisite M.P.E.P. guidelines for a non-final first Office Action since the amendment was presented but clearly indicated to require a further search and consideration. Therefore, Applicants respectfully request reconsideration and withdrawal of the finality of the current Office Action.

Rejections Under 35 U.S.C. § 102

Claims 14-39 stand rejected under 35 U.S.C. § 102 as being anticipated by Chee et al. The Office alleges that Chee et al. describe a method which provides an array composition having a substrate with discrete sites and a population of microspheres containing first and second subpopulations where each microsphere contains a plurality of different target analytes. In particular, the Office asserts that Chee et al. describe a plurality of different target analytes covalently attached to each microsphere within a subpopulation allegedly because this reference describes target nucleic acids having two target domains. Each target domain within a single target nucleic acid is alleged to be a target analyte. Chee et al. is further asserted to describe a plurality of different target analytes covalently attached to each microsphere allegedly because the microspheres can contain identifier binding ligands (IBL), which are target analytes for decoder binding ligands (DBL). Chee et al. also is alleged to describe each microsphere having a plurality of different IBLs. The Office concludes that the purported immobilized nucleic acids having first and second target domains and/or the plurality of different IBLs are the same as the claimed plurality of different target analytes covalently attached to each microsphere.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Office must show that the

single reference cited as anticipatory art describes all the elements of the claimed invention. Applicants maintain that Chee et al. does not anticipate the claimed invention because the cited reference fails to describe microsphere subpopulations each having a plurality of different target analytes where the plurality of different target analytes are covalently attached to the microspheres.

The claimed invention is directed to various methods of analyzing a target analyte. In particular, the application defines a target analyte to be a molecule when it describes:

> The present invention is directed to the detection of patient sample components or target analytes. By "patient sample components" or "target analytes" or grammatical equivalents herein is meant any molecule in the sample which is to be detected, with proteins and nucleic acids being preferred , and nucleic acids being particularly preferred.

Application at page 6, lines 28-31 (emphasis added).

Therefore, a target analyte of the claimed invention is a molecule or molecular entity. It is this molecular entity that is to be detected in the methods of the invention. As a molecular entity to be detected, a target analyte is distinct from, and does not refer to a portion of, the target molecule to be detected. Similarly, a target analyte is distinct from, and does not refer to another component used in an assay to detect the target molecule.

The Office asserts that Chee et al. describe a target nucleic acid that contains two target domains, alleging that the two domains of the same molecule constitute different target analytes. Applicants submit that the target domains of a nucleic acid are distinct from a target analyte of the claimed invention because they are portions of the same molecule. For example, Chee et al. describe the use of target domains as subsequences of a target to hybridize probes or primers for amplification or detection of a target nucleic acid (see, for example, the Summary and col. 10, lines 20-24). Because the target domains described in Chee et al. constitute portions of a molecule they are not the molecule in a sample to be detected and cannot anticipate a target analyte as is claimed by the invention.

The Office also asserts that Chee et al. describe a target-probe ligation product immobilized on microspheres where the microspheres further contain identifier binding ligands

(IBLs), alleging that the IBLs constitute target analytes for decoder binding ligands (DBLs). Further asserted is that Chee et al. describes microspheres containing a plurality of different IBLs, alleging that each constitutes an analyte for a DBL.

Applicants similarly submit that the IBLs, used to decode the location capture probes on an array, are distinct from the claimed target analytes of the invention because they do not constitute the molecule in a sample to be detected. An IBL is described by Chee et al. as being:

> [A] compound that will specifically bind to a corresponding decoder binding ligand (DBL) to facilitate the elucidation of the identity of the bioactive agent attached to the bead.

Id., col. 44, lines 10-14 (emphasis added).

According to the description in Chee et al., an IBL merely helps in determining the identity of a bioactive agent. Elucidation is accomplished by decoding the spatial location of the beads on an array and IBLs are exemplified as capture probes (see, for example, col. 49, line 63 through col. 51, line 20). Because an IBL is a component used in the assay described by Chee et al. for facilitating the identity of a bioactive agent, it cannot be the actual molecule detected in the sample. Furthermore, there is no indication in the cited passages of Chee et al. that the IBLs are from an individual, whereas the claims require target analytes from an individual. Therefore, an IBL is distinct from the target analytes of the claimed invention and their inclusion on microspheres together with a target-probe ligation product cannot anticipate the invention as claimed.

As stated in Applicants' previous responses, Chee et al. may describe a plurality of target analytes but he does not describe a plurality of different target analytes covalently attached to a microsphere. In particular, the passages relied upon by the Examiner does not describe a plurality of different target analytes attached covalently to a microsphere because the cited passage is directed to the design of probes. For example, Chee et al. describes that:

> [P]robes can be made using the techniques disclose herein to detect target sequences such as the gene for nonpolyposis colon cancer, the BRCAl breast cancer gene, P53, which is a gene associated with a variety of cancers, the Apo E4 gene that indicates a greater risk of Alzheimer's disease, allowing for easy

> presymptomatic screening of patients, mutations in the cystic fibrosis gene, cytochome p450s or any of the others well known in the art.

Id., col. 56, lines 23-32.

Although the passage above describes several target sequences to which probes can be made, nothing in the above passage describes the attachment of two or more target analytes obtained from different individuals to microspheres. Similarly, other passages cited by the Office also do not describe the attachment of two or more target analytes from different individuals to microspheres. Because Chee et al. does not describe the attachment of different target analytes from different individuals each to a single microsphere, this reference cannot anticipate the invention as claimed. Therefore, Applicants submit that the rejection is moot and respectfully request its withdrawal.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

David A. Gay
Registration No. 39,200

4370 La Jolla Village Drive, Suite 700
San Diego, CA 92122
Phone: 858.535.9001 DAG:GSS
Facsimile: 858.597.1585
Date: August 1, 2005

Please recognize our Customer No. 41552 as our correspondence address.